REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 1-40 are pending in this application. The claims have been amended as set forth above to correct informalities.

REJECTIONS UNDER 35 U.S.C. §112

Claims 19, 21, 27, 32, and 37 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Withdrawal of this rejection is respectfully requested in view the following remarks.

Claim 19 has been amended to include chemical names of the surfactants previously identified solely by their trademarks/trade names.

Claim 32 has been amended to depend from claim 29, which provides antecedent basis for the term "non-ionic surfactant."

With respect to claims 19, 21, 33, and 37, the Examiner asks how a drug can be partially dissolved in the same medium without a solvent present in the emulsion. It is important to note that claims 19, 21, 33, and 37 are directed to a self-emulsifying formulation, not an emulsion. The self-emulsifying formulation does not become an emulsion until it is introduced into an aqueous media. The hydrophobic drug is soluble in the oil phase of the self-emulsifying formulation. Since the oil phase dissolves the hydrophobic drug, the oil phase functions as a solubilizer/solvent for the hydrophobic drug. It is possible to have both solubilized and solid nanoparticles of the hydrophobic drug in the self-emulsifying formulation during and/or after preparation if the drug loading exceeds the drug solubility in the self-emulsifying formulation. In this example, the solubilized drug would provide high solubility after emulsification in an aqueous medium, while the nanoparticles would impart rapid dissolution.

REJECTIONS UNDER 35 U.S.C. §102

I. Claims 1, 2, 4-7, 9-14, 18, 22, 23, 25-28, 38, and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Aviv et al. (U.S. Patent No. 5,496,811). This rejection is respectfully traversed.

Aviv et al disclose an oil-in-water emulsion comprising a hydrophobic drug, an oily phase, a surfactant/emulsifier, and an aqueous component, where the mean droplet size of the oil phase is in a range from 0.05 to 0.5 microns. The submicron droplets are formed only after incorporating the drug and surfactant/emulsifier in an oil phase and dispersing the oil phase in an aqueous component. The examples describe subjecting the oil-in-water emulsion to additional processes to form the submicron droplets. Aviv et al neither disclose nor teach that the hydrophobic drug is in nanoparticulate form prior to forming the oil-in-water emulsion. It should be noted that the formulation recited in the claims has not been introduced into an aqueous media, is not an oil-in-water emulsion, and does not form an oil-in-water emulsion until introduced into an aqueous media. Stable nanosuspension in self-emulsifying formulation gives rise to high drug loading and rapid dissolution.

From the foregoing, Aviv et al do not anticipate the invention as recited in claims 1, 2, 4-7, 9-14, 18, 22, 23, 25-28, 38, and 39. Withdrawal of the rejection of claims 1, 2, 4-7, 9-14, 18, 22, 23, 25-28, 38, and 39 in view of Aviv et al. is respectfully requested.

II. Claims 1, 2, 4-14, 18, 22, 23, 25-28, 38, and 39 were rejected under 35 USC 102(b) as being anticipated by Friedman et al (U.S. Patent No. 6,113,921). This rejection is respectfully traversed.

Friedman et al. teach a pharmaceutical composition comprising submicron droplets of a water-insoluble drug. Each droplet includes an oily liquid comprising the drug, an emulsifier, and a surfactant. The submicron droplets are formed only after incorporating the drug and surfactant/emulsifier in an oil phase and dispersing the oil phase in an aqueous phase. The examples describe subjecting the oil-in-water emulsion to additional processes to form the submicron droplets. Friedman et al neither disclose nor teach that the water-insoluble drug is in nanoparticulate form prior to forming the oil-in-water emulsion. It should be noted that the formulation recited in the claims has not been introduced into an aqueous media, is not an oil-in-water emulsion, and does not form an oil-in-water emulsion until introduced into an aqueous

media. Stable nanosuspension in self-emulsifying formulation gives rise to high drug loading and rapid dissolution.

From the foregoing, Friedman et al do not anticipate the invention as recited in claims 1, 2, 4-14, 18, 22, 23, 25-28, 38, and 39. Withdrawal of the rejection of claims 1, 2, 4-14, 18, 22, 23, 25-28, 38, and 39 in view of Friedman et al is respectfully requested.

III. Claims 1-6, 9-31, 34-36, and 38-40 were rejected under 35 U.S.C. 102(b) as being anticipated by Yiv et al (U.S. Patent No. 6,245,349). This rejection is respectfully traversed.

Yiv et al disclose a drug formulation including a drug, a phospholipid component, a polypropylene glycol, a high HLB surfactant, and optionally water and/or oil. In concentrate form, the drug formulation does not include water. In diluted form, the drug formulation includes water. The diluted drug formulations are referred to as oil-in-water emulsions. Yiv et al disclose that the diluted drug formulation is such that it is filter sterilizable. Filter sterilization includes passing the composition through a 0.22 micron filter. Submicron average particle sizes are reported for the diluted drug formulation but not for the concentrated drug formulation. Yiv et al neither disclose nor teach that the drug is in nanoparticulate form in the concentrated drug formulation. It should be noted that the formulation recited in the claims has not been introduced into an aqueous media, is not an oil-in-water emulsion, and does not form an oil-in-water emulsion until introduced into an aqueous media. Stable nanosuspension in self-emulsifying formulation gives rise to high drug loading and rapid dissolution.

From the foregoing, Yiv et al do not anticipate the invention as recited in claims 1-6, 9-31, 34-36, and 38-40. Withdrawal of the rejection of claims 1-6, 9-31, 34-36, and 38-40 in view of Yiv et al is respectfully requested.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated January 12, 2007, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC3244R1).

Respectfully submitted,

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